UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff/Counter-Defendant,

v.

BLUEWILLOW BIOLOGICS, INC.,

Defendant/Counter-Plaintiff.
_____/

Case No. 2:21-cv-10312

HONORABLE STEPHEN J. MURPHY, III

CLAIM CONSTRUCTION OPINION AND ORDER

Plaintiff Trutek Corporation obtained United States Patent Number 8,163,802 (the '802 patent) for one of its technologies. ECF 1, PgID 2–3. The patented technology allows consumers to apply Plaintiff's "products in and around their nasal passages to reduce reactions to airborne allergens and to reduce or eliminate reactions to viral infections" like the flu. *Id.* at 3. Plaintiff's technology eliminates viruses "by establishing an electrostatic charge in and around nasal passages." *Id.*

Defendant Bluewillow Biologics sells a product called NanoBio Protect. *Id.* at 4; ECF 9, PgID 72. The product is also applied to the nasal passages and "help[s] reduce germs on skin that can cause infections." ECF 1-1, PgID 10. NanoBio Protect operates by establishing an "electro-kinetic charge" that attracts harmful particles and kills them "on contact." *Id.* at 11.

Plaintiff sued Defendant for patent infringement. ECF 1. Plaintiff alleged that Defendant's product infringed the '802 patent because "[t]he ability to lessen the reactions to airborne contaminants by creating an electrostatic charge around a

person's nasal passages is inherent in [Plaintiff]'s formulations and manufacturing processes." *Id.* at 6. Defendant denied Plaintiff's allegations and argued that the '802 patent was "invalid and has not been . . . infringed." ECF 9, PgID 84. Defendant also counterclaimed that it had not violated the '802 patent and requested a declaratory judgment of the '802 patent's invalidity. *Id.* at 84–86. The Court retained the request for a declaratory judgment but dismissed the first counterclaim because it was redundant. ECF 15.

The Court also issued an order requiring the parties to propose dates for a claim construction hearing. ECF 33. After the parties responded, ECF 34, the Court set a claim construction briefing and hearing schedule, ECF 35. The parties then filed *Markman* briefs and responses. ECF 37; 38; 40; 41. And the Court held a claim construction hearing on November 15, 2022. For the following reasons, the Court will adopt (1) Plaintiff's construction of a "person of ordinary skill in the art" of pharmaceutical formulation and (2) Plaintiff's constructions of the four claim terms at issue.

BACKGROUND

The specification for the '802 patent describes the invention as "products and methods that involve the use of products . . . for restricting the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages." ECF 37, PgID 573. The electrostatic field reduces "the inflow of airborne contaminants to the nasal passages by capturing the contaminants and keeping them from entering the body." *Id.* at 572.

The '802 patent contains twenty-three claims, four of which are at issue. *Id.* at 576–77; *see* ECF 38, PgID 593 (Claims 1, 2, 6, and 7). Claim 1 lays out a method for applying a formulation to the nasal passages that creates an electrostatically charged field that attracts harmful particles and renders them harmless. ECF 37, PgID 537.

> A method for *electrostatically inhibiting* harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
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> a) *electrostatically attracting* the particulate matter to the thin film;
>
> b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide *adequate impermeability* to the thin film; and,
>
> c) inactivating the particulate matter by adding at least one ingredient that would *render said particulate matter harmless*.

Id. at 576 (emphasis added). Claim 2 contains the formulation that is applied to the nasal passages, which includes a cationic agent and a biocidic agent. *Id.*

> A formulation for *electrostatically inhibiting* harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
>
> a) *electrostatically attracts* the particulate matter to the thin film;
>
> b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide *adequate impermeability* to the thin film; and,
>
> c) inactivates the particulate matter and *renders said particulate matter harmless*.

Id. (emphasis added). Claim 6 derives from Claim 2 and provides that one of the cationic agents in Claim 2 "is Benzalkonium Chloride." *Id.* Claim 7 is also a derivative

of Claim 2; it provides that one of the biocidic agents in Claim 2 "is Benzalkonium Chloride or Lysine HCL." *Id.*

Within Claims 1 and 2, the construction of four terms are disputed by the parties: (i) "electrostatically inhibiting"; (ii) "electrostatically attracting"; (iii) "adequate impermeability"; (iv) and "renders said particulate matter harmless." *Id.* The Court must determine the meaning of the four disputed terms to decide whether the four claims are definite.

LEGAL STANDARD

Patents grant inventors "the right to exclude others from making, using, offering for sale, selling, or importing the patented invention, in exchange for full disclosure of an invention." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) (internal quotations marks and quotation omitted). A patent must "describe the exact scope of an invention" by providing (1) specifications about the invention and (2) claims that "point out and distinctly claim the subject matter which the applicant regards as his invention." *Id.* (cleaned up). Likewise, 35 U.S.C. § 112(b) requires that the specification of a patent "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or joint inventor regards as the invention." "Claims of a patent are short and concise statements, expressed with great formality, of the metes and bounds of the patented invention. Each claim is written in the form of a single sentence." *Recticel Automobilesysteme GmbH v. Auto. Components Holdings, LLC*, No. 2:10-cv-14097, 2012 WL 1276003, at *2 (E.D. Mich. Apr. 16, 2012). "[A] bedrock principle of patent

law [is] that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Innova/Pure Water v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004) (collecting cases).

I. Claim Construction

"Claim construction is the manner in which courts determine the meaning of the terms in the claim. The construction of claims is simply a way of elaborating the normally terse claim language: in order to understand and explain, but not to change, the scope of the claims." *Recticel*, 2012 WL 1276003, at *2 (quoting *Scripps Clinic & Rsch. Found. V. Genentech, Inc.*, 927 F.2d 1565, 1580 (Fed. Cir. 1991)). Claim construction is necessary "when the meaning or scope of technical terms and words of art is unclear . . . and requires resolution in order to determine obviousness." *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997); *see also Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy").

"[T]he court has the power and obligation to construe as a matter of law the meaning of language used in the patent claim." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). To encourage "uniformity in the treatment" of a patent, "all issues of construction" are reserved for the Court. *Markman*, 517 U.S. at 390. "Courts can neither broaden nor narrow the claims to give the patentee something different than what he has set forth. No matter how great the temptations of fairness or policy making, courts do not rework claims. They only interpret them."

E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1440, 1443 (Fed. Cir. 1988) (quotation omitted). And courts need not "repeat or restate every claim term in order to comply with the ruling that claim construction is for the court. Claim construction is . . . not an obligatory exercise in redundancy." *Ethicon*, 103 F.3d at 1568.

When faced with an ambiguity in the terms of the claim, courts must look to "the claim itself, the specifications, [and] the prosecution history" to resolve the ambiguity. *Ascion, LLC v. Tempur Sealy Int'l, Inc.*, No. 5:17-cv-403, 2021 WL 3197553, at *3 (E.D. Ky. July 28, 2021) (*citing Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). If the claim language is clear on its face, consideration of other intrinsic evidence is limited to determining whether the patentee intended to deviate from the clear language of the claims. *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quotation omitted). But if intrinsic evidence cannot resolve the ambiguity, courts may consider extrinsic evidence. *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004). Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (quotation and citation omitted).

Claim terms "are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art." *Thorner v. Sony Comp. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012); *see also Compuserve Inc.*, 256 F.3d at

1332 (noting that claims are always construed from the point of one skilled in the relevant art). A person having ordinary skill in the art "is a hypothetical person who is presumed to be aware of all the pertinent prior art. The actual inventor's skill is not determinative." *Custom Accessories Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 962 (Fed. Cir. 1986). Courts may consider several factors to determine the appropriate level of skill, including: "type of problems encountered in art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *Id.* (footnote omitted).

II. Indefiniteness

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). "It cannot be sufficient that a court can ascribe *some* meaning to a patent's claims." *Id.* at 911. Rather, the proper inquiry is whether "a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Id.* at 910.

"Indefiniteness is a matter of claim construction." *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008). "A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998) (citation omitted). The party asserting

patent invalidity has the burden to establish indefiniteness by clear and convincing evidence. *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1366 (Fed. Cir. 2014).

DISCUSSION

The Court will first resolve the definition of a "person of ordinary skill in the art." *Thorner*, 669 F.3d at 1365. After, the Court will address the four terms in dispute: (i) "electrostatically inhibiting"; (ii) "electrostatically attracting"; (iii) "adequate impermeability"; (iv) and "renders said particulate matter harmless."

I. Person of Ordinary Skill in the Art

The definiteness of a claim is assessed from the perspective of a "person of ordinary skill in the art." *Thorner*, 669 F.3d at 1365. Here, neither the patent claims nor the specifications reference a definition of a "person of ordinary skill in the art." *Id.*; *see* ECF 37, PgID 571–77.

The parties and their experts agreed that the relevant art is pharmaceutical formulation. ECF 40, PgID 711; ECF 38-8, PgID 634. But they disagreed on the necessary qualifications for a person of ordinary skill in the art of pharmaceutical formulation. Defendant's expert, Mansoor Amiji, claimed that a person with ordinary skill in pharmaceutical formulation would "ha[ve] at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation." ECF 38-3, PgID 626, 634. Plaintiff's expert, Edward Lemmo, characterized Amiji's claim about a person with skilled in the art as someone who would have "extraordinary skill." ECF 40,

PgID 732, 737. And he countered Amiji's position by opining that a person with ordinary skill in pharmaceutical formulation would not need an advanced degree but would be a technician who could "create the formulations described in the patent." *Id.* at 737. Lemmo also stated that a person skilled in the art would be familiar with the chemical ingredients listed in the patent, "know enough chemistry and biology to be familiar with cationic agents and biocidic agents," have knowledge of airborne particles including viruses and bacteria, and "know enough undergraduate physics to understand electrostatic fields as well as the principles of electrostatic attraction and repulsion, adhesion, and cohesion." *Id.* at 738. He maintained that the person "would be able to decipher or understand the various options that they have available to them as recited in the patent." ECF 49-2, PgID 996. The parties' disagreement therefore boils down to whether the person with ordinary skill in the art of pharmaceutical formulation would have both an undergraduate degree and a master's degree or just an undergraduate degree.

Altogether, the level of scientific knowledge described by both Lemmo and Amiji would seem to require at least an undergraduate degree in relevant science. Both experts referenced knowledge of physics, chemistry, cationic agents, and biocidic agents. ECF 40, PgID 738. Lemmo suggested that an undergraduate degree was necessary to obtain that knowledge. *Id.* And while Amiji claimed that an advanced degree was necessary to attain the necessary degree of knowledge, he offered no support for that claim aside from a statement that he would personally qualify as a person of ordinary skill in the art. *See* ECF 38-3, PgID 634–35. Furthermore, his

claim that the person would have "at least an M.S. degree" was qualified by the phrase "or the equivalent." *Id.* at 634. The qualifier suggests that an advanced degree is not necessarily required to understand the science and that a certain level of technical experience might also suffice to qualify a person as skilled in the art.

In sum, because Amiji failed to adequately support his claim that an advanced degree was required, the Court will adopt Plaintiff's definition of a "person of ordinary skill in the art" of pharmaceutical formulation. *Thorner*, 669 F.3d at 1365. The Court will now turn to the four terms in dispute.

II. Electrostatically Inhibiting

The term "electrostatically inhibiting" features in both Claim 1 and Claim 2. ECF 37, PgID 576. Claim 1 provides:

> A method for *electrostatically inhibiting* harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
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> a) electrostatically attracting the particulate matter to the thin film;
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> b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
>
> c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

Id. (emphasis added). Claim 2 provides:

> A formulation for *electrostatically inhibiting* harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
>
> a) electrostatically attracts the particulate matter to the thin film;

> b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
> c) inactivates the particulate matter and renders said particulate matter harmless.

Id. (emphasis added). Plaintiff suggested "electrostatically inhibiting" be construed as referring to a "formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto, and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless." *Id.* at 560–61. Put another way, "[t]he meaning of '[electrostatically inhibiting]' is using an electrostatic field to attract or repel harmful particles." *Id.* at 546. Defendant provided no construction of its own. *See* ECF 38, PgID 595–98. Instead, it argued that the meaning of the term was indefinite because the patent lacked "objective guidance or criteria" like data or test results

showing that the formulations actually inhibit harmful particulate matter from infecting an individual. *Id.* at 596–97.[1]

But Defendant's argument fails in light of the '802 patent's claim language and prosecution history. The term "electrostatically inhibiting" refers to one of the formulation's key functions: using an electrostatic field to trap and neutralize harmful particles. It references both the electrostatic means by which the formulation operates and the aim of that formulation. The claim refers to the function as a "method" for "inhibiting harmful particulate matter," and then the claim describes the three steps necessary for carrying out the inhibition: attracting the particulate matter, holding it in place, and "inactivating" it. ECF 37, PgID 576. On balance, the plain language of the claim communicates a definite meaning to the term "electrostatically inhibiting" that aligns with Plaintiff's proposed construction.

[1] Defendant lodged a similar argument for all four of the disputed claim terms. *See* ECF 38, PgID 596–98; 600; ECF 38-3, PgID 640–41. At bottom, Defendant argued that the terms are indefinite because Plaintiff failed to include test results or other such data in the patent to prove that the patented technology does what it purports to do. *See* ECF 38, PgID 596–98; 600; ECF 38-3, PgID 640–41. The argument is unavailing. Whether Plaintiff included test results or other such data in the patent does not affect whether it is definite. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) ("We have made clear that the written description requirement does not demand either examples or an actual reduction to practice."). Indeed, "a disclosure is sufficient even if it would require that one skilled in the art conduct some experimentation." *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 791 (Fed. Cir. 1983). And the '802 patent requires no undue experimentation by the formulator. *See* ECF 37, PgID 576 ("The desired results may be achieved by varying the ingredients and their amounts by those skilled in the art without undue experimentation."). Defendant's argument about the lack of test results and other such data in the patent is not persuasive.

The prosecution history of the "802 patent also supports adoption of Plaintiff's proposed construction. The originally drafted patent used the language "electrostatically preventing" rather than "electrostatically inhibiting." *Id.* at 561, 581. The patent examiner recommended changing that language to "electrostatically inhibiting" because the term "electrostatically preventing" did not "enable any person skilled in the art to which it pertains . . . to make and use the invention commensurate in scope with the[] claims." *Id.* at 581. In other words, the prosecution examiner recommended the term "electrostatically inhibiting" be employed so that a person of ordinary skill in the art of pharmaceutical formulation could effectively use the technology. And "when a word is changed during prosecution, the change tends to suggest that the new word differs in meaning in some way from the original word." *Ajimototo Co., Inc. v. Int'l Trade Comm'n*, 932 F.3d 1342, 1351 (Fed. Cir. 2019). The patent examiner's recommended change thus favors Plaintiff's proposed construction because it reflects a definite meaning of the term "electrostatically inhibiting" that enables a person skilled in the art to use the patented technology.

Defendant contended that the patent examiner's recommendation made the terms even more ambiguous because a pathogen would not be rendered harmless if it were only inhibited, as opposed to prevented, from "enter[ing] the individual's nostril." ECF 38, PgID 603. But Defendant cited no authority for that statement. *See id.* And the '802 patent is clear that the technology operates by capturing and holding harmful particles inside the nasal passages. *See* ECF 37, PgID 576 (noting that the formulation is "applied to the skin or tissue of nasal passages" in the form of a thin

film and holds harmful particulate matter to the thin film). Indeed, the very design of the technology requires the particles to be held inside the nasal passages before they can be rendered harmless. *Id.* at 573 ("It is a further object of the invention to provide a composition that can be applied . . . to the area around the exterior of and/or slightly *inside* the edge of the nostril that will inactivate, kill, or render harmless a microorganism, which has been captured by the composition.") (emphasis added). Thus, a particle could enter nasal passages and still be rendered harmless. In all, Defendant's argument falls short because its claim that the technology can only function if it prevents particles from entering the nasal passages is unsupported.

Defendant also claimed that the patent examiner's recommendation was made in the context of enablement, not construction. ECF 41, PgID 768. Thus, according to Defendant, the patent examiner's recommendation should "not preclude a finding of indefiniteness." *Id.* But the patent examiner's recommendation involved a near identical analysis to that of a claim's construction. The patent examiner stated that "preventing" should be replaced with "inhibiting" because the specification "does not enable any person skilled in the art to which it pertains . . . to make and use the invention commensurate in scope with the[] claims." ECF 37, PgID 581. And the purpose of the language replacement was to permit "any person skilled in the art" to "make and use [the invention]." *See* 35 U.S.C. § 112(a). In other words, the patent examiner's use of "enablement" was simply a reference to the technology's capabilities as part of the larger evaluation of whether a person skilled in the art could use the technology. The examiner's enablement inquiry therefore lacks a meaningful

distinction from a definiteness analysis here. For all the reasons stated above, the Court will adopt Plaintiff's construction of the term "electrostatically inhibiting."

III. Electrostatically Attracting

The term "electrostatically attracting" appears in both Claim 1 and Claim 2. ECF 37, PgID 576. Claim 1 provides:

> A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
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> a) *electrostatically attracting* the particulate matter to the thin film;
>
> b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
>
> c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

Id. (emphasis added). Claim 2 provides:

> A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
>
> a) *electrostatically attracts* the particulate matter to the thin film;
>
> b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
>
> c) inactivates the particulate matter and renders said particulate matter harmless.

Id. (emphasis added). As with the previous term, Plaintiff suggested a construction of "electrostatically attracting" to describe a "formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne

particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped." *Id.* at 560.

Defendant argued that Plaintiff had provided no examples, data, or test results that showed the technology "electrostatically attract[s]" particulate matter. ECF 38, PgID 596–97 ("Nor does the []'802 Patent provide any information concerning the objective parameters a [person of ordinary skill in the art] would need to assess to determine whether a formulation operates to 'electrostatically attract' . . . harmful particulate matter.").

The Court will adopt Plaintiff's proposed construction because the term "electrostatically attracting" has a meaning that is clear from the plain language of the patent. Claims 1 and 2 begin by describing the technology's purpose and method before listing the three processes involved: attracting the particulate matter, holding it in place, and inactivating it. ECF 37, PgID 576. The term "electrostatically attracting" is a description of the first process, in which particulate matter is attracted through electrostatic means to the thin film that is applied to the nasal passages. *Id.* at 573–76. And Plaintiff's proposed construction, which states that the term describes a formulation that "creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped," *id.* at 560, reflects the nature of that process.

On balance, because its ordinary meaning is clear from the plain language of the patent, the Court will adopt Plaintiff's construction of the term "electrostatically attracting."

IV. Adequate Impermeability

The term "adequate impermeability" features in both Claim 1 and Claim 2. Claim 1 provides:

> A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
>
> a) electrostatically attracting the particulate matter to the thin film;
>
> b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide *adequate impermeability* to the thin film; and,
>
> c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

Id. at 576 (emphasis added). Claim 2 provides:

> A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
>
> a) electrostatically attracts the particulate matter to the thin film;
>
> b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide *adequate impermeability* to the thin film; and,
>
> c) inactivates the particulate matter and renders said particulate matter harmless.

Id. (emphasis added). Plaintiff argued that "adequate impermeability" refers to the "thin film holding harmful particles in place and inhibiting them from penetrating the thin film and contacting the skin or tissue of an individual's nasal passages. This is done by varying the concentration of ingredients . . . [,]thereby adjusting the adhesion and cohesion of the thin film." *Id.* at 562 (emphasis omitted). Defendant

argued that "adequate impermeability" is a subjective term of degree that provided no guidance on "how impermeable the thin film must be, the purpose for the impermeability, what level of impermeability is required to be 'adequate' with respect to the . . . harmful particulate matter, or how to test the level of impermeability." ECF 38, PgID 598.

The Court agrees that "adequate" is a term of degree. "Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014) (citation omitted). "While a claim employing a term of degree may be definite where it provides enough certainty to one of skill in the art when read in the context of the invention, a term of degree that is purely subjective and depends on the unpredictable vagaries of any one person's opinion is indefinite." *Intell. Ventures I LLC v. T-Mobile USA, Inc.*, 902 F.3d 1372, 1381 (Fed. Cir. 2018) (cleaned up).

The Court will adopt Plaintiff's proposed construction for two reasons. First, when read in the context of the invention, the term "adequate impermeability" refers to a part of the technology that allows harmful particulate matter to be held in place long enough to be rendered harmless. It is an expression of the qualities inherent in the thin film that allow the technology to work according to its specification. Put another way, "adequate impermeability" describes the amount of impermeability achieved by adjusting the adhesion and cohesion of the thin film—a core function of the technology. *See* ECF 37, PgID 572–73 ("Objects of the Invention"). Plaintiff's

proposed construction, which stated that the term "adequate impermeability" refers to the "thin film holding harmful particles in place and inhibiting them from penetrating the thin film and contacting the skin or tissue of an individual's nasal passages" by "adjusting the adhesion and cohesion of the thin film," is therefore appropriate. *Id.* at 562–63 (emphasis omitted).

Second, the patent successfully provides a standard by which to define the scope of "adequate impermeability." *See Interval Licensing*, 766 F.3d at 1368–69 (holding that the terms "in an unobtrusive manner" and "does not distract user" were indefinite because they failed to provide a standard for determining their scope). In fact, the '802 patent contains ten formulation tables with concentration ranges that can be used by a formulator to create an adequately impermeable thin film. *See* ECF 37, PgID 574–76. The tables contain multiple ranges within which the ingredient concentrations may fall. *Id.* And a person of ordinary skill in the art of pharmaceutical formulation could work with the ingredients to make the technology function properly. *Id.* at 576 ("The desired results may be achieved by varying the ingredients and their amounts by those skilled in the art without undue experimentation."). To be sure, varying the ingredient percentages could change the potency or relative efficacy of the resulting solution. ECF 49-2, PgID 1000. But the technology will function properly so long as the concentrations are within the assigned ranges. ECF 40, PgID 713, 746; ECF 49-2, PgID 1005.

Defendant argued that the concentration ranges in the ten tables made the term "adequate impermeability" indefinite. ECF 38, PgID 600. But the concentration

ranges in the tables are not indefinite. For one, the patent includes specific numerical percentage ranges. ECF 37, PgID 574–76. And "the recitation of specific numerical ranges in a claim does not raise an issue of whether a claim is definite." MPEP § 2173.05(c). For another, the concentration ranges create numerical boundaries for a pharmaceutical formulator. ECF 37, PgID 574–76; *Interval Licensing*, 766 F.3d at 1370 (noting that claims must provide objective boundaries for those of skill in the art). And the ranges are precise. ECF 37, PgID 574–76. Each table lists the relevant ingredients and details the concentration ranges to the half-percentage point. *Id.* While the ranges would be sufficiently definite even "without reference to a precise numerical measurement," *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1335 (Fed. Cir. 2010), the ranges are certainly precise enough to be considered definite for purposes of the '802 patent's validity because they are not merely "a continuum, defined by what . . . characteristic is most important to a particular user." *Ventures*, 902 F.3d at 1381. Instead, the ranges establish specific parameters that allow the technology to function so long as the formulator stays within them.

Defendant also argued that the concentration ranges were subjective because they could lead to many outcomes that may or may not enable the technology to work properly. ECF 41, PgID 770–71. Purely subjective requirements that allow "the end-user experience" to be the "final arbiter" of the outcome are considered indefinite. *Ventures*, 902 F.3d at 1381. But here, "adequate impermeability" is not purely subjective or dependent on the "vagaries of any one person's opinion." *Id.* It is defined and constrained by precise numerical concentration ranges in the tables provided in

the patent. That the formulator would need to adjust the concentrations to "optimize the formulation . . . would not be undue." ECF 40, PgID 746. In Lemmo's words: "Formulators do this all the time. It is not 'rocket science.'" *Id.*

In all, when read in the context of the invention, the term "adequate impermeability" refers to a part of the technology that allows harmful particulate matter to be held in place long enough to be rendered harmless. Neither the term of degree nor the presence of ten formulation tables detract from that plain meaning. The Court will therefore adopt Plaintiff's proposed construction of the term "adequate impermeability" because it provides "enough certainty to one of skill in the art when read in the context of the invention." *Interval Licensing*, 766 F.3d at 1370 (citation omitted).

V. Render Said Particulate Matter Harmless

The term "render said particulate matter harmless" features in both Claim 1 and Claim 2. ECF 37, PgID 576. Claim 1 provides:

> A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
>
> a) electrostatically attracting the particulate matter to the thin film;
>
> b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
>
> c) inactivating the particulate matter by adding at least one ingredient that would *render said particulate matter harmless*.

Id. (emphasis added). Claim 2 provides:

> A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
>
> a) electrostatically attracts the particulate matter to the thin film;
> b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
> c) inactivates the particulate matter and *renders said particulate matter harmless*.

Id. (emphasis added). Plaintiff urged the Court to construe the phrase to refer to the manner in which the formulation attracts harmful particles, holds them in place, and uses a cationic agent and a biocidic agent to neutralize, inactivate, or kill the particles. ECF 40, PgID 724; *see also* ECF 37, PgID 562 ("The term 'renders said particulate matter harmless' refers to one or more microorganisms being captured, killed, and inactivated.") (alteration and emphasis omitted). According to Plaintiff, "[a] person having ordinary skill in the art would understand this construction." ECF 37, PgID 562. Their expert Lemmo likewise stated that the phrase "refers to preventing at least some of the infectious material from passing into the system of the host by inactivating or killing it, thereby rendering it 'less harmful.'" ECF 40, PgID 752.

Defendant proposed no construction but argued that the phrase was indefinite because the term "'harmless' is a general concept that can be highly subjective depending on the . . . specific particulate matter that is to be rendered 'harmless.'" ECF 38, PgID 600. Defendant claimed it is impossible for a single technology to

render harmless such a large range of particulate matter. *Id.* at 600–01. And defense expert Amiji maintained that the phrase was indefinite because it did not specify how much harmful particulate matter must be captured to render it harmless or what ingredient composition was necessary for each pathogen. ECF 38-3, PgID 640–41.

Again, the Court will adopt Plaintiff's proposed construction because the plain meaning of the term "render said particulate matter harmless" is clear. The patent presents the three steps associated with the technology's functioning: attracting the particulate matter, holding it in place, and "inactivating" it. ECF 37, PgID 576. "Render said particulate matter harmless" refers to the third step, and describes the way in which the formulation neutralizes, inactivates, kills, or otherwise renders harmless the harmful particulate matter that is captured by the thin film in the nasal passages. To be sure, Defendant is correct that "harmless" may be pathogen-dependent, but the patent contains ten formulation tables and ingredient concentration percentages for the formulator to use so that the technology is responsive to a specific pathogen. ECF 37, PgID 574–76. In other words, the patent is designed to respond to the varied definitions of "harmless" that arise when the technology encounters different pathogens. Defendant's argument is therefore unpersuasive. All told, the Court will adopt Plaintiff's construction of the term "render said particulate matter harmless."

CONCLUSION

The Court will adopt Plaintiff's construction of a "person of ordinary skill in the art" of pharmaceutical formulation. The Court will also adopt Plaintiff's constructions of the four disputed claim terms.

With the claim construction issues now resolved, the Court believes the parties would benefit from participating in alternative dispute resolution. The Court will therefore refer the parties to Mr. Patrick Seyferth for settlement discussions and mediation.[2] The mediation must take place no later than February 17, 2023.

ORDER

WHEREFORE, it is hereby **ORDERED** that the Court **ADOPTS** Plaintiff's definition of a "person of ordinary skill in the art" and Plaintiff's proposed constructions of the terms "electrostatically inhibiting," "electrostatically attracting," "adequate impermeability," and "render said particulate matter harmless."

WHEREFORE, it is hereby **ORDERED** that the Court **REFERS** the case to Mr. Patrick Seyferth for mediation and settlement discussions and **ORDERS** the parties to proceed in compliance with Local Rule 16.4. The mediation and settlement discussions must occur **no later than February 17, 2023**. The parties must contact Mr. Seyferth and provide him with a copy of this order as soon as practicable and must **NOTIFY** the Court of the date of the mediation session once it is scheduled.

[2] Patrick Seyferth is a private attorney and founding member of the firm Bush Seyferth, PLLC. He can be reached at (248) 822-7802 and at Seyferth@bsplaw.com.

IT IS FURTHER ORDERED that Mr. Seyferth must **NOTIFY** the Court within seven days of completion of the mediation, "stating only the date of completion, who participated, whether settlement was reached, and whether further [alternative dispute resolution] proceedings are contemplated." E.D. Mich. L.R. 16.4(e)(6). If a settlement is reached, the parties must **NOTIFY** the Court immediately upon completion of the mediation and must **SUBMIT** a proposed order of dismissal within 21 days. *Id*. at 16.4(e)(7). If a settlement is not reached, the parties must **NOTIFY** the Court within five days of the completion of the mediation.

SO ORDERED.

s/ Stephen J. Murphy, III
STEPHEN J. MURPHY, III
United States District Judge

Dated: January 10, 2023

I hereby certify that a copy of the foregoing document was served upon the parties and/or counsel of record on January 10, 2023, by electronic and/or ordinary mail.

s/ David P. Parker
Case Manager